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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/554,387 | 06/29/2000 | BERND FABRY | H-3185-PCT/U | 2050 |

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EXAMINER

JIANG, SHAOJIA A

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,387

Applicant(s)

FABRY, BERND

Examiner

Shaojia A. Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's response filed on February 11, 2002 in Paper No. 15. Currently, claims 11-30 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939) and Hasegawa et al. in view of Miettinen et al. (EP 0594612B1), and Hidvegi (5,277,910) for the reasons of record stated in the Office Action dated August 29, 2001.

Applicant's remarks filed on February 11, 2002 in Paper No. 15 with respect to this rejection of claims 11-30 made under 35 U.S.C. 103(a) have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Again, Applicant arguments that "none of the cited references teaches or suggests the use of a conjugated fatty acid" in the claimed method herein and that the Examiner has failed to establish a prima facie case upon the cited references, are not found persuasive. As discussed in the previous Office Action (August 29, 2001),

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Jandacek teaches broadly the usefulness of phytosterols such as β -sitosterol along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms including any conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, in the instant claimed method. Moreover, Miettinen et al. teaches broadly the usefulness of fatty acids esters of β -sitosterol (β -sitostenol) and β -sitostanol containing approx. 2-22 carbon atoms and up to about 3 double bonds in the instant claimed method for reducing serum cholesterol content in a mammal, i.e., rapeseed oil is well known that rapeseed oil contains about 90% unsaturated fatty acids having one or more double bonds. Hasegawa's teaching that the particular fatty acid, linoleic acid, and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals provides further motivation for the instant method. Thus, the employment of a conjugated fatty acid herein is seen to be suggested by the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining a phytosterol and the particular unsaturated fatty acid, a conjugated fatty acid having from about 6 to about 24 carbon atoms, or a ester of a phytostenol (phytosterol) such as a ester of β -sitosterol (β -sitostenol) carboxylic acid having from 2 to 22 carbon atoms and up to about 3 double bonds known useful for the same purpose in a composition to be administered would improve the therapeutic effect of the combination composition for reducing serum cholesterol content in a mammal, absent evidence to the contrary.

Since all active composition components herein are known to useful to reduce serum cholesterol content in a mammal, it is considered prima facie obvious to combine

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them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected based on the well settled principle set forth *In re Kerkhoven* regarding combination inventions. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); *In re Merck. & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

Therefore, the three criteria for a prima facie case are met for the instant case based on above discussion.

As discussed in the previous Office Action (August 29, 2001), Applicant's data of Examples and Table 1 in the specification at pages 8-9 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. It is noted that lauric acid in lauric acid β -sitostanol ester or lauric acid β -sitostenol ester employed in the testing herein is not even an unsaturated carboxylic acid (having no double bond), which is not a conjugated fatty acid. Thus, these two compounds are not within the scope of the claimed invention. Therefore, the results on these two compounds are not relevant to the nonobviousness of the claimed invention. Accordingly, the results on the tests of the employment of lauric acid β -sitostenol or lauric acid β -sitostanol (as example of phytostenol esters) combined with conjugated

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linoleic acid in the composition in the composition shown in Table 1, (e.g., Compositions 3-4) in the specification applied to rats are not deemed relevant as to unexpected results of the claimed invention over the prior art.

The results on the tests of the employment of β -sitostenol or β -sitostanol combined with conjugated linoleic acid in the composition in the composition shown in Table 1 in the specification applied to rats have been fully considered but are not deemed persuasive as to unexpected results over the prior art because the results from the test on the employment of β -sitostenol or β -sitostanol combined with conjugated linoleic acid in the composition do not show any additive effects on reducing the cholesterol content in rats after 12 hours. After 24 or 48 hours the results merely demonstrate less than additive therapeutic effects of β -sitostenol and conjugated linoleic acid in the composition on serum cholesterol levels in rats. Further, the specification provides no side-by-side comparison between the employment of **unconjugated fatty acids** and **conjugated fatty acids** with β -sitostenol or β -sitostanol in the claimed method herein. The comparison merely between the combination herein and a phytostenol compound or a conjugated fatty acid alone in the specification herein is insufficient to clearly demonstrate any possible unexpected supra additive effects for the combination over the cited prior art (i.e., the combination of unconjugated fatty acids with β -sitostenol or β -sitostanol in the claimed method). Moreover, the tests herein merely employ the combination of two particular phytostenols, β -sitostenol or β -sitostanol in combination with the particular conjugated fatty acid, conjugated linoleic acid. Thus, the evidence in the testing on is not commensurate in scope with the

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claimed invention and does not demonstrate criticality of a claimed range of phytosterol compounds and conjugated fatty acids herein. See MPEP § 716.02(d). Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. See MPEP § 716.02(c). Therefore, no clear and convincing evidence of nonobviousness or unexpected results for the combination in the claimed method presented in specification herein is seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 10, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200